DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Cypher
Docket No.: 2003E-0407

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

JAN - 6 2006

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,563,146, filed by Wyeth, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Cypher, the medical device claimed by the patent.

The total length of the regulatory review period for Cypher is 814 days. Of this time, 513 days occurred during the testing phase and 301 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: February 1, 2001.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on February 1, 2001.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: June 28, 2002.

   FDA has verified the applicant's claim that the premarket approval application (PMA) for Cypher (PMA P020023) was initially submitted on June 28, 2002.

3. The date the application was approved: April 24, 2003.

   FDA has verified the applicant's claim that PMA P020023 was approved on April 24, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas S. Szatkowski
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